Attachment 2

MAY - 8 2012

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K120149

1. **Submitter's Identification:**

Sakura Seiki Co., Ltd.
46-1, Shinden
Chikuma, Nagano 387-0018
Japan
Phone: 81-26-273-3583
Fax: 81-26-273-2584

Date Summary Prepared: April 16th 2012

2. **Name of the Device:**

Proprietary name:
SKYTRON *Integrity 215 Steam Sterilizer*
SKYTRON Integrity 215 SG Steam Sterilizer
Sakura Steam Sterilizer ASSV-AB09
Sakura Steam Sterilizer ASSV-AB09E

Common Name: Steam Sterilizer
Regulation: 21CFR Part 880.6880, Class II
Product Code: FLE

3. **Common or Usual Name:**

Common name: Steam Sterilizer
Classification name: Sterilizer, Steam

4. **Predicate Device Information:**

Steris Amsco Century Gravity and Prevacuum Sterilizers K030789

5. **Description:**

The SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers are Class II, Product Code FLE Medical Devices as defined by CFR§880.6880 and defined for use in healthcare facilities.

The SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers provide efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizers also dry items that have been sterilized with wet steam.

6. **Intended Use:**

Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer are available in the following configuration.

Note: **Sakura Steam Sterilizer ASSV-AB09E / SKYTRON Integrity 215 SG Steam Sterilizer equip the integrated steam generator.**

21.5" x 21.5" x 38" chamber size, Single Door Prevacuum and Gravity.

Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer are equipped with the following factory-programmed sterilization cycle values. The following factory-programmed cycles are validated according to ANSI/AAMI ST8: 2008.

Cycle	Maximum Validated Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash 1	One unwrapped, nonporous instrument no	270 F (132 C)	3 minutes	1 minute

(IU 1)	heavier than 0.22 lbs. (100 gram)			
Flash 2 (IU 2)	Maximum of six (6) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	1 minute
Prevacuum 270	Maximum of six (6) double-wrapped instrument trays, maximum weight 25 pound (11.3kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	30 minutes
Prevacuum 275	Maximum of six (6) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	275 F (135 C)	3 minutes	30 minutes

Express Prevacuum (IU 3)	Maximum of six (6) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier.	270 F (132 C)	4 minutes	3 minutes
Gravity 1	Maximum of twelve (12) - fabric packs.	250 F (121 C)	30 minutes	15 minutes
Gravity 2	Maximum of six (6) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each.	270 F (132 C)	15 minutes	30 minutes
Liquid	Maximum of three (3) 1,000 mill-liter containers with vented closures. This cycle is intended for non-patient contacting devices only.	250 F (121 C)	45 minutes	0 Minute
Leak Test	Empty Chamber, test time of 15 minutes.	N/A	N/A	N/A
Warm Up	Empty Chamber	270 F (132C)	4 minutes	3 minutes

Bowie-Dick Test	Bowie-Dick Test Pack	273 F (134 C)	3.5 minutes	2 Minute

Note:

- Prevacuum 270 - Adjusting the Dry Time to be 15 minutes allows the sterilization of 12 fabric packs (maximum).
- Gravity 2 - Adjusting the Steam Purge Time to 10 minutes, the Sterilize Time to 25 minutes, and the Dry Time to 15 minutes allows the sterilization of 12 fabric packs (maximum).
- "IU" means "Immediate Use" cycle.
- Liquid cycle is for non-patient contact use only.

7. Technological Characteristics

Comparison to Predicate Device
The proposed sterilizers offered within this submission are equipped with the same options offered under the predicate device, in design and construction except for: predicate device offers a stainless steel frame in addition to the carbon steel, subject device offers stainless steel option for piping, subject device utilizes 2 types of air filters and an Integrated Water recirculation system.

EFFECTIVENESS:
Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} reduction. **Sakura Seiki Co., Ltd.** validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, the sterilizers were validated to meet the requirements of AAMI/ANSI ST8: 2008.

The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (May 2005).*

SAFETY:
The SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura*

Steam Sterilizer ASSV-AB09E Steam Sterilizers complies with the following safety standards:

IEC 60601-1-2:2007
IEC61010-1 (2nd Edition) 2008 / CSA C22.2 No.61010-1
IEC61010-2-040: 2005
CISPR11: 2009 ED5.0: AMENDMENT1: 2010
IEC61000-3-2:2005 ED3.0: AMENDMENT1:2010
IEC61000-3-3:2008 ED2.0 (EMC) - PART 3-3
IEC61000-4-2: 2008 ED2.0 (EMC) - PART 4-2
IEC61000-4-3: 2006 ED3.0 +AMENDMENT1: 2007+AMENDMENT2:2010 (EMC)
IEC61000-4-4: 2004 ED2.0 +AMENDMENT1:2010
IEC61000-4-5: 2005 ED2.0
IEC61000-4-6: 2003 ED2.0+AMENDMENT1:2004+AMENDMENT1:2006
IEC61000-4-8: 2009 ED2.0
IEC61000-4-11: 2004 ED2.0
American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section VIII Division 1 2010 Edition: Rules for the Construction of Pressure Vessels.

HAZARDS-FAILURE OF PERFORMANCES
Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.
To avoid failure, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer's manufacturer's maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incident of sterilizer malfunction or sterilization process failure is relatively rare considering the wide spread use of steam sterilizers. Further, there are no reports in the literature of patient infection that have resulted from steam sterilizer failure.

The technology designed in the SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers provide microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

USER INFORMATION

Sakura Seiki Co., Ltd. provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed User's Manual and other labeling.

Sakura Seiki Co., Ltd. also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

8. **Performance Data:**

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers. The device passed all of the tests based on pre-determined Pass/Fail criteria.

9. **Conclusions:**

The data from consensus standard testing and comparison to the predicate device show that the SKYTRON *Integrity 215 Steam Sterilizer, SKYTRON Integrity 215 SG Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09, Sakura Steam Sterilizer ASSV-AB09E* Steam Sterilizers are as safe and effective as the legally marketed predicate device.

Therefore **Sakura Seiki Co., Ltd.** conclude that the each of the sterilizers included under this submission are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sakura Seiki Company, Limited
C/O Ms. Dawn Tibodeau
Responsible Third Party Official
TUV SUD America, Incorporated
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

AUG 17 2012

Re: K120149
Trade/Device Name: Sakura Steam Sterilizer ASSV-AB09
Sakura Steam Sterilizer ASSV-AB09E
Skytron Integrity 215 Steam Sterilizer
Skytron Integrity 215 SG Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: April 20, 2012
Received: April 23, 2012

Dear Ms. Tibodeau:

This letter corrects our substantially equivalent letter of April 20, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, Genera Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number (if known): K120149

Device Name:
Sakura Steam Sterilizer ASSV-AB09
Sakura Steam Sterilizer ASSV-AB09E
Skytron Integrity 215 Steam Sterilizer
Skytron Integrity 215 SG Steam Sterilizer

Indications For Use:

Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilizer incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSV-AB-09 / Skytron Integrity 215 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AB09E / Skytron Integrity 215 SG Steam Sterilize are available in the following configuration.

Note: **Sakura Steam Sterilizer ASSV-AB09E / SKYTRON Integrity 215 SG Steam Sterilizer equip the integrated steam generator.**

21.5" x 21.5" x 38" chamber size, Single Door Prevacuum and Gravity.

Prescription Use _____ **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use** X **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment 1

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Cycle	Maximum Validated Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash 1 (IU 1)	One unwrapped, nonporous instrument no heavier than 0.22 lbs. (100 gram)	270 F (132 C)	3 minutes	1 minute
Flash 2 (IU 2)	Maximum of six (6) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	1 minute
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	This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier.			
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Liquid	Maximum of three (3) 1,000 mill-liter containers with vented closures. This cycle is intended for non-patient contacting devices only.	250 F (121 C)	45 minutes	0 Minute
Leak Test	Empty Chamber, test time of 15 minutes.	N/A	N/A	N/A
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Note:

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- "IU" means "Immediate Use" cycle.
- Liquid cycle is for non-patient contact use only.

Elizabeth F. Clarence-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120149